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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,121	01/18/2002	Randolph M. Howes		7866

7055 7590 10/17/2006  
GREENBLUM & BERNSTEIN, P.L.C.  
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RESTON, VA 20191

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/050,121		HOWES, RANDOLPH M.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Frank I. Choi		1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10,11 and 16-46 is/are pending in the application.
- 4a) Of the above claim(s) 11,17-28,30-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10,26,29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

In view of the Amended Appeal Brief filed on 1/25/2006, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

### ***Status of Claims***

According to the Amended Appeal Brief (1/25/2006), Claims 10, 11, 16-46 are pending. Claims 11, 17-28, 30-46 are withdrawn as directed to a non-elected invention. Claim 10, 16, 29 are directed the elected invention. The Examiner notes that the Amendment dated (6/13/2005) did not contain a complete listing of the claims; none of the withdrawn claims were listed, claim 13 was not listed as canceled (See Amendment (8/25/2003), pg. 4, claim 13). The Examiner respectfully requests that the Applicant provide a complete listing of claims 1-46 with

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appropriate status identifiers (except for canceled and not entered claims, the claim language of the claims, including withdrawn claims, must be set forth) (See 37 CFR 1.121(c)).

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Igarashi et al..

Igarashi et al. disclose separately adding NaOCl and H<sub>2</sub>O<sub>2</sub> into a tube (pages 1466, 1467.

The Examiner interprets the claim as being directed to a source of peroxide, a source of hypochlorite anion, which is separate from the source of peroxide and a catheter, in which there does not necessarily have to be an interaction between the three components, and the target site of a tumor is an intended use. A “catheter” is a tubular medical device. Merriam-Webster’s Collegiate Dictionary (10<sup>th</sup> Ed. 1998), pg. 181). As such, since the prior art discloses a tube and the separate addition of NaOCl and H<sub>2</sub>O<sub>2</sub>, the prior art anticipates the claim. The intended use of the claimed system does not patentably distinguish the claimed system from the prior art.

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Claims 16, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al. in view of Vincent et al., Gurchumelidze (US Pat. 5,512,045), Rosen et al. and the acknowledged prior art.

Weiss et al. disclose a method of inhibiting the development of malignant ascites due to spillage of cancer cells during surgery, for example during laparotomy or intra-abdominal cancer, by irrigating with hydrogen peroxide solution and local administration of hydrogen peroxide by intraperitoneal injections (See entire reference, especially, pages 98, 102).

Vincent et al. disclose the use of a sodium hypochlorite solution as an irrigant or single dose in cancer surgery to reduce the risk of local implantation of tumor cells and treatment of Ehrlich ascites tumor cells with hypochlorite solution which resulted in prolongation of survival of mice (See entire reference, especially, pages 997,1005).

Gurchumelidze discloses that intestinal decompression has become an important procedure in abdominal surgery and that in patients with small bowel obstruction due to tumors there is an accumulation of ingested fluid and intestinal gas within the tract (Column 1, lines 10-21). A device is disclosed which allows intubation of gastrointestinal organs which require decompression and irrigation which device constitutes in part of a quadruple lumen catheter which provides for suction and conduit for irrigation/lavage solution (Column 2, lines 64-68).

Rosen et al. discloses that the a well described mechanism for the formation of singlet oxygen is the interaction of hypochlorite and H<sub>2</sub>O<sub>2</sub>, that the other reaction products are water and chloride ion and that singlet oxygen is the mechanism by which leucocytes act on tumor cells (Pgs. 4808, 4809).

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Applicant acknowledges that singlet oxygen is effective against tumor cells and cancer (Paragraph 009). Further, it is acknowledged that the photodynamic method for producing singlet oxygen has several drawbacks, including the problem of untargeted portions of the body being exposed and expense (Paragraphs 013,014,015). It is disclosed that using a peroxide-hypochlorite anion system singlet oxygen is produced which is identical to that obtained by dye-sensitized photooxidation. (Paragraph 017). It is acknowledged that singlet oxygen is the principle bacterial oxidizing agent employed by human neutrophils and monocyte phagosomes (Paragraph 019). Applicant acknowledges that singlet oxygen is a very short-lived species of oxygen (Paragraph 084).

The prior art discloses method of treating tumor cells resulting from spillage of cancer cells during surgery with hydrogen peroxide solution. The difference between the prior art and the claimed invention is that the prior art does not disclose administering an irrigation or irrigating solution that combines at least one source of peroxide and at least once source of hypochlorite ion or a system which contains a source of hypochlorite, a source of peroxide and a catheter. However, the prior art amply suggests the same as the prior art individually teaches in the art the use of sodium hypochlorite solution or hydrogen peroxide solution for treating cancer or tumor cells which may become locally transplanted due to surgery and a catheter which allows for irrigation of intestinal tract during abdominal surgery. Further, the prior art discloses that hydrogen peroxide and sodium hypochlorite are reactive species and that product of the reaction is singlet oxygen which is known to be effective in the treatment of cancer and to be very short lived. As such, it would have been well within the skill of and one of ordinary skill in the art to irrigate the surgical area during cancer surgery with a hydrogen peroxide solution and a

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sodium hypochlorite solution using said catheter with the expectation that the two solutions would be effective in inhibiting tumor formation due to transplantation of tumor cells during surgery, to keep said solutions separate until time of use due as they are reactive species and that the catheter would be effective for irrigation of the desired site and reduce the risk of complications due to the presence of intestinal gases and fluids.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 10, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carroll (US Pat. 6,375,634) in view of Ameta et al. (Asian J. Chem. Rev., 1(2);106-124 (1990)) and the acknowledged prior art.

Carroll discloses treatment of a tumor using probe with a central passage for irrigant and a coaxial suction cannula where the irrigant can be a hydrogen peroxide and hypochlorite bleach solution which does not cause significant collateral damage to healthy tissues and without causing microscopic shedding of tumor cells (Column 2, lines 47-53, Column 11, lines 35-62, Column 12, lines 16-28).

Ameta et al. discloses that singlet oxygen can be prepared by photosensitization in which oxygen is passed into a solution containing a dye and a substrate exposed to visible or u.v. light or by the reaction between sodium hypochlorite and hydrogen peroxide in which the other products are NaCl and water (Pgs. 108, 109).

Applicant acknowledges that singlet oxygen is effective against tumor cells and cancer (Paragraph 009). Further, it is acknowledge that the photodynamic method for producing singlet

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oxygen has several drawbacks, including the problem of untargeted portions of the body being exposed and expense (Paragraphs 013,014,015). It is disclosed that using a peroxide-hypochlorite anion system singlet oxygen is produced which is identical to that obtained by dye-sensitized photooxidation. (Paragraph 017). It is acknowledged that singlet oxygen is the principle bacterial oxidizing agent employed by human neutrophils and monocyte phagosomes (Paragraph 019). Applicant acknowledges that singlet oxygen is a very short-lived species of oxygen (Paragraph 084).

The prior art discloses treatment of a tumor using probe with a central passage for irrigant and a coaxial suction cannula where the irrigant can be a hydrogen peroxide and hypochlorite bleach solution which does not cause significant collateral damage to healthy tissues and without causing microscopic shedding of tumor cells. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of sodium hypochlorite and hydrogen peroxide from separate sources to treat tumors. However, the prior art amply suggests the same as it is known in the art to prepare solutions containing sodium hypochlorite and hydrogen peroxide for treatment of tumors, that sodium hypochlorite and hydrogen peroxide react to form singlet oxygen which is effective against cancer and tumor cells and that single oxygen is a short lived species. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective in treating tumors. Further, one of ordinary skill in the art, knowing that singlet oxygen is a short-lived species, would be motivated to separately combine the peroxide and hypochlorite at the point of use so as to ensure that singlet oxygen is available for treatment of the cancer or tumor cell.



Examiner has duly considered Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

To the extent that Applicant's arguments may be applicable, the following applies:

As a preliminary matter, Applicant's 1.131 affidavit is insufficient to antedate Carroll.

Carroll discloses the use of a tube for delivery of a irrigation solution containing hydrogen peroxide and hypochlorite bleach solution for treatment of tumors and has an effective filing date based on a provisional application of November 19, 1997. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Carroll reference.

While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897).

The affidavit fails to provide evidence that Applicant conceived the use of separate sources of hypochlorite and peroxide for treatment of tumors, a system contain separate sources of hypochlorite and peroxide and a catheter for treatment of tumors or an irrigation solution containing a source of hypochlorite and a source of hypochlorite for treatment of cancer or tumor cells seeded as a result of surgery prior to the effective filing date of Carroll. The only mention of tumoricidal activity is in relation to use of singlet oxygen in an irrigating system for wound cavities, however, there is no indication as to what would contained in the irrigation system other than singlet oxygen.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the Carrol

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reference. No entry of the affidavit indicates the use of separate sources of hypochlorite and peroxide for treatment of tumors, a system contain separate sources of hypochlorite and peroxide and a catheter for treatment of tumors or use of an irrigation solution containing a source of hypochlorite and a source of hypochlorite for treatment of cancer or tumor cells seeded as a result of surgery. Applicant's argument as to genus/species does not overcome the rejection as this is not a genus/species situation. See *In re Tanczyn*, 146 USPQ 298 (CCPA 1965) (It is not sufficient to show in a rule 131 affidavit an invention outside that being claimed was made prior to the reference date); *Ex parte Marhold*, 231 USPQ 904 (BdPatApp&Int 1984)(if a 131 affidavit is relied upon, the evidence must establish that they reduced to practice the entire invention being claimed).

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Carrol reference to either a constructive reduction to practice or an actual reduction to practice. The last entry is dated March 16, 1996, the earliest filing date is based on a provisional application filed on January 22, 2001.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

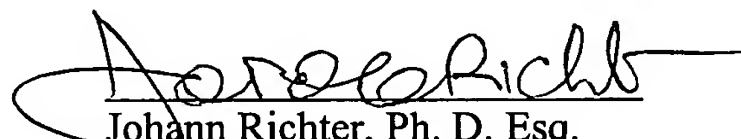
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
October 5, 2006

  
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